K120131

510(k) Summary

FEB 10 2012

As required by 807.92

1. Company Identification

Konica Minolta Medical & Graphic, Inc.
No.1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan
Establishment Registration Number: 3004485675

2. Submitter's Name and Address

Shigeyuki Kojima
Manager
Regulations and Standards Section, Quality Assurance Center
No. 1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan
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3. Date of Submission

January 13, 2012

4. Device Trade Name

Direct Digitizer, REGIUS SIGMA2

5. Classification

Class II , 90 MQB, 21 CFR 892.1650.

6. Predicate Device

Direct Digitizer, REGIUS SIGMA, 510(k) number: K103703

7. Indications for Use

The Direct Digitizer, REGIUS SIGMA2 is an X-ray image reader which uses a stimulable phosphor plate (Plate) as X-ray detector installed in a separate cassette. It reads the image recorded on the Plate and transfers the image data to an externally connected device such as a host computer, an order input device, an image display device, a printer, an image data filing device, and other image reproduction devices. It is designed and intended to be used by trained medical personnel in a clinic, a radiology department in a hospital and in other medical facilities.

This device is not intended for use in mammography.

8. Device Description

The Direct Digitizer, REGIUS SIGMA2 is a compact X-ray image reader which uses a stimulable phosphor plate (Plate) as X-ray detector installed in a

cassette, and reads the image recorded on the Plate by inserting a cassette in the entrance slot of this device. By means of laser scan and photoelectric method, this device reads the X-ray image data created in form of a latent image on the Plate exposed by an external X-ray generating device, and converts the read data into digital.

The device is comprised of a reading unit with cassette containing Plate.

Plates and cassette remain unchanged from the predicate device, REGIUS SIGMA.

The image data transfer to an externally connected device such as a host computer, an order input device, an image display device, a printer, an image data filing device, and other image reproduction devices.

The basic operations of REGIUS SIGMA2 and the predicate device, REGIUS SIGMA, such as a starting, a shut down, a registration-of-patient, a setting of a various condition are operated with the Medical Image Processing Workstation, ImagePilot (operator console) which is cleared 510(k), K071436.

The modification was made from the REGIUS SIGMA to the REGIUS SIGMA2 to increase processing capacity. To increase the processing capacity, the firmware (device mechanical control software) of the reading unit is modified. The outline is as follows.

The processing capacity is increased by controlling the feed sequence.

(1) Increasing the speed of removal of Plate from cassette and the sequence of storage into cassette

(2) Increasing the erasing speed by changing the erasing LED

The feed sequence related to Image Quality (Reading speed, Open/Close timing of sub-scanning nip) is not changed.

9. Performance Testing

Performance data from non-clinical testing of the REGIUS SIGMA2 is compared with data from the predicate device, REGIUS SIGMA. This comparison showed that the REGIUS SIGMA2 performed as well as the predicate device.

10. Substantial Equivalence to Predicate Device

The predicate device and the REGIUS SIGMA2 are the X-ray image reader which use the same stimulable phosphor plate (Plate) as X-ray detector installed in a separate cassette. The principals of operation and technological characteristics of the predicate device and the REGIUS SIGMA2 is the same. The performance test results show that there is no new safety and efficacy issue of the REGIUS SIGMA. The indications for use of REGIUS SIGMA remain unchanged from the predicate device.

For details, please refer to Section 8, Device description.

11. Safety Information

The REGIUS SIGMA2 has been tested and shown to meet the requirements of the following standards.

Safety standard : IEC60601-1 Ed.2(1988)+ A1(1991)+A2(1995)

Electromagnetic Compatibility : IEC60601-1-2 Ed.3(2007)

Radiation safety : 21 CFR 1040.10, IEC60825-1(1993)+A1(1997)+A2:2001

The Risk Analysis for the REGIUS SIGMA2 was conducted on the basis of ISO14971, "Medical devices – Application of risk management to medical devices". As a result of risk control measures, the risk associated with all of the identified hazards was reduced to an acceptable level.

12. Conclusion

Comprehensively, we judged that the REGIUS SIGMA2 has the same technological characteristics as the predicate devices. This 510(k) has demonstrated substantial equivalence as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

KONICA MINOLTA MEDICAL & GRAPHIC, INC
Mr. Russell D. Munves
Consultant
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Two Grand Central Tower, 25th Floor
140 East 45th Street
NEW YORK NY 10017

FEB 10 2012

Re: K120131
Trade/Device Name: Direct Digitizer, REGIUS SIGMA2
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: January 13, 2012
Received: January 17, 2012

Dear Mr. Munves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) :

Device Name : Direct Digitizer, REGIUS SIGMA2

Indications for Use:

The Direct Digitizer, REGIUS SIGMA2 is an X-ray image reader which uses a stimulable phosphor plate (Plate) as X-ray detector installed in a separate cassette. It reads the image recorded on the Plate and transfers the image data to an externally connected device such as a host computer, an order input device, an image display device, a printer, an image data filing device, and other image reproduction devices. It is designed and intended to be used by trained medical personnel in a clinic, a radiology department in a hospital and in other medical facilities.
This device is not intended for use in mammography.

Prescription Use__X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-off
Office of In Vitro Diagnostic Devices
Evaluation and Safety

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